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10/675,603	09/29/2003	Eric C. Luo	43305.12.0.43.1 fka 3200-	6336

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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04/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,603	LUO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,17-21 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,17-21 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 01/21/2009.

Claims 13-16, 22-42 have been canceled, and claim 43 has been added.

Claims 1-12, 17-21 and 43 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The rejection of claims 1-4, 9, 11, 13, 14, 17, 19-21 under 35 U.S.C. 102(b) as being anticipated by US 4,938,970 ('970).

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12, 17-21 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are amended to recite that: "the inorganic base comprising an inorganic hydroxide present in an amount of about 0.75 to 2.0% of a topically applied formulation or a drug reservoir of a drug delivery system or patch". With careful recourse to the specification, the claimed amount of 0.75 to 2.0% is actually the only part of the amount of organic base that is additional to the amount of the inorganic base that is necessary to neutralize that the acid addition salt and/or other base-neutralizable species. In page 11, paragraph 0039 of the present specification, applicants disclosed that:

> "For formulations and patches in which the agent is in the form of an acid addition salt, and/or wherein there are additional species in the formulations or systems that can be neutralized by or react with the **inorganic base** (i.e., acidic inactive ingredients), the **amount** of inorganic hydroxide is preferably the total of (1) the **amount** necessary to neutralize the acid addition salt and/or other base-neutralizable species (i.e., the "acidic species"), plus (2) about 0.5-4.0 wt %, preferably about 0.5-3.0 wt %, more preferably about 0.75-2.0 wt %, of the formulation or drug reservoir."

Therefore, amount of inorganic base of 0.75 to 2.0% as instantly claimed is not the amount disclosed by the present disclosure. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-12, 17-21 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,938,970 ('970).

The present claims are directed to topical composition comprising local anesthetic, carrier, sodium hydroxide, wherein the composition has pH of 8.0-13.0, and the organic base present in an amount of 0.75-2.0%.

US '970 teaches aqueous solution for topical composition comprising local anesthetic including lidocaine, and sodium hydroxide to bring the pH of the composition to 6.85-8.0 (abstract; col.3, lines 20-30, 42-43; col.6, lines 7-10). The composition further comprises cations which read on irritation mitigating agent, in absence of

disclosure of any irritation mitigating agents (col.3, lines 39-40). The teaching of the reference implies using both acidic and non-acidic species of the anesthetic.

Although US '790 teaches pH of topical composition up to 8.0, however, US '970 does not explicitly teach the amount of hydroxide releasing agent as claimed by amended claims 1 and 43, or pH over 8.0 as claimed by claims 5 and 18, the formulation as claimed by claim 6, the amount of enhancement of the delivery as claimed by claims 7 and 8.

Regarding such values of pH and amounts of hydroxide releasing agent, one having ordinary skill in the art would have determined such amounts according to specific intended use. Regarding enhancement of the delivery of the formulation, it is expected to be the same from formulation having the same ingredients. Further, topical formulations such as gel, lotions and creams are all known for topical use.

Therefore, it would have been obvious to one having ordinary in the art at the time of the invention to provide topical aqueous formulation comprising local anesthetic and hydroxide releasing agent having pH value up to 8.0, and further adjust the amount of the hydroxide releasing agent according to the specific site of application to obtain the desired pH in order to achieve safe topical formulation.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

6. Claims 1-12, 17-21, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,497 ('497).

US '497 teaches medicated plaster having an exposed surface with pH of 7.0 or higher comprising active agent including lidocaine hydrochloride (abstract; col.7, lines 7-9; col.9, lines 15-17). PH is adjusted using sodium hydroxide (col.8, lines 65-67). US '497 teaches using basic substance in an amount of 0.1 to 10 moles per mole of medicine (col.9, lines 5-7). This teaching implies that the amount of the basic substance is not only to neutralize the medicine, but can be as much as 10 times more than the medicine casing alkaline pH when neutralizing the formulation.

Although US '479 teaches pH of topical composition up to 8.0, however, the reference does not explicitly teach the amount of hydroxide releasing agent as claimed by amended claims 1 and 43, or pH over 8.0 as claimed by claims 5 and 18, the formulation as claimed by claim 6, the amount of enhancement of the delivery as claimed by claims 7 and 8.

Regarding such values of pH and amounts of hydroxide releasing agent, one having ordinary skill in the art would have determined such amounts according to specific intended use. Regarding enhancement of the delivery of the formulation, it is expected to be the same from formulation having the same ingredients. Further, topical formulations such as gel, lotions and creams are all known for topical use.

Therefore, it would have been obvious to one having ordinary in the art at the time of the invention to provide topical formulation comprising local anesthetic and hydroxide releasing agent having pH value higher than 7.0, and further adjust the amount of the hydroxide releasing agent according to the specific site of application to obtain the desired pH in order to achieve safe topical formulation.

Response to Arguments

7. Applicant's arguments filed 01/21/2009 have been fully considered but they are not persuasive. Applicants traverse the claims over US '970 and US '497 by arguing that US '970 teaches pH up to 8.0 and NaOH is used by the reference for different purpose than the present claims as it is used as buffering agent to keep pH at or near neutral, and US '497 teaches pH of around 7 and 8. Applicants argue that this intended use results in a structural difference.

In response to this argument, applicants' attention is directed to the scope of the present invention that is drawn to composition, and all the elements of the composition recited by claims 1-4, 9, 11, 13, 14, 17, 19-21 are disclosed by the cited references. In response to applicant's argument that NaOH used by the reference for a different purpose, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The reference disclosed administration of effective amount of local anesthetics. There is no structure difference between the prior art products and the present product, since both have the same structure, and are expected to have the same function because materials and their properties and functions are inseparable. The references disclosed pH up to 8.0, therefore, pH of 8.0 was known by the prior art and the present claims recite range of about 8.0 to 13.0. It has been held that where the claimed ranges overlap or lie inside

ranges disclosed by the prior art, a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Regarding the claims that recite pH of about 8.5 to 11.5, it has been further held that a prima facie case of obviousness exists where the claimed ranges and the prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Meals Corp. of America v. Banner,* 778 F2d 775, 227 USPQ 773 (Fed. Cir. 1985). The discovery of a new action underlying a known process does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, Inc. v. Union Oil Co. of Cal.,* 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). This is believed to be applicable here because anticipation is the epitome of obviousness.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-12, 17-21 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,582,724. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. The local anesthetics are recited in claim 37 of the issued patent. Therefore, the claims of the issued patent anticipate the present claims.

10. Claims 1-12, 17-21 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,673,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. Therefore, the claims of the issued patent anticipate the present claims.

11. Claims 1-12, 17-21 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,835,392. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. The local anesthetics are recited in claim 43 of the issued patent. Therefore, the claims of the issued patent anticipate the present claims.

12. Claims 1-12, 17-21 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,586,000 in view of US 5,993,836 ('836). The present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent and active agent.

The difference between the present claims and the claims of the issued patent is that the issued claims do not recite local anesthetic as the drug to be delivered by the claimed device and method.

US '836 teaches topical and transdermal delivery of local anesthetics that have rapid onset and additionally convenient and not messy (col.3, lines 25-30, 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver topical or transdermal formulation comprising

hydroxide releasing agent and active agent as claimed by US '836, and replace the active agent by local anesthetic as disclosed by US '836, motivated by the teaching of US '836 that local anesthetics are desirable to be delivered transdermally or topically to provide rapid onset of local anesthesia, with reasonable expectation of having topical or transdermal formulation comprising hydroxide releasing agent and local anesthetic that has rapid onset of action to relieve pain rapidly and effectively from the patient in need of such treatment.

13. Claims 1-12, 17-21 and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 51-52 of copending Application No. 10/863,432. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the claims of the copending application are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent and local anesthetic.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments filed 01/21/2009 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' intention to finally resolve the obviousness double patenting rejection at such point where there is an indication of allowable subject matter, at which time Applicant will consider and file any terminal disclaimer that is deemed proper.

However, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611